JAN 2 4 2001

K003990

Special 510(k) Summary
for
Parietex® TET 1208D and TET 1409D Meshes

1. SPONSOR

Sofradim Production
116 Avenue du Formans
01600 Trevoux
France

Contact Person: Mr. Patrice Becker
Telephone: 011 33 4 74 08 90 00

Date Prepared: December 22, 2000

2. DEVICE NAME

Proprietary Name: Sofradim Parietex® Surgical Meshes
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

Sofradim Parietex® Surgical Mesh	K982532
Sofradim Parietene Surgical Mesh	K990014

4. DEVICE DESCRIPTION

The proposed Parietex® TET 1208D and TET 1409D Meshes are identical in intended use and fundamental technology to the parent Parietex® Meshes. Modifications are limited to a slight design change which helps in placing the mesh around the inguinal cord during inguinal hernia repair.

The parent Parietex® Meshes required use of a suture whereas the modified Parietex® TET 1208D and TET 1409D Mesh has an additional Velcro-like component which simply wraps around the inguinal cord, reducing the need for the suture component to close the two "arms" of the mesh around the cord during the surgery.

5. INTENDED USE

The Sofradim Parietex® Surgical Meshes and the Parietex® TET 1208D and 1409D Mesh are intended for the reinforcement of tissues during surgical repair of inguinal hernias.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modified Parietex® TET 1208D and TET 1409D Meshes with the material modification are substantially equivalent in design, function, and intended use to the parent Parietex® Meshes cleared for marketing under K982532.

The fundamental technology and characteristics of the proposed Parietex® TET 1208D and TET 1409D Meshes and the predicate parent Parietex® Meshes are identical. Both the parent Parietex® Mesh and the Parietex® TET 1208D and TET 1409D Meshes are intended for inguinal hernia repair. The only difference between the new Parietex® TET 1208D and TET 1409D Meshes and the parent Parietex® Meshes is the slightly modified design. The test data submitted as part of this 510(k) demonstrate that the minor difference in design does not adversely affect the device.

7. TESTING

Sofradim performed mechanical and characterization testing on the modified Parietex® TET 1208D and TET 1409D and found the materials to be similar in properties and characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2001

Sofradim Production
c/o Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K003990
Trade Name: Sofradim Parietex® TET 1208D
and TET 1409D Surgical Meshes
Regulatory Class: II
Product Code: FTL
Dated: December 22, 2000
Received: December 26, 2000

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003990

Device Name: Sofradim Parietex® TET 1208D and TET 1409D Surgical Meshes

Indications For Use:

The Sofradim Parietex® TET 1208D and TET 1409D Surgical Meshes are intended for the reinforcement of tissues during surgical repair of inguinal hernias.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003990

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)